EUROPEAN
COMMISSION

Brussels, 21.6.2018
C(2018) 4021 final

COMMISSION IMPLEMENTING DECISION

of 21.6.2018

concerning, in the framework of Article 31 of Directive 2001/83/EC of the European Parliament and of the Council, the marketing authorisation granted by Decision C(2001)818 for “Targretin - bexarotene", medicinal product for human use

(Text with EEA relevance)

(ONLY THE ENGLISH TEXT IS AUTHENTIC)

COMMISSION IMPLEMENTING DECISION

of 21.6.2018

concerning, in the framework of Article 31 of Directive 2001/83/EC of the European Parliament and of the Council, the marketing authorisation granted by Decision C(2001)818 for “Targretin - bexarotene", medicinal product for human use

(Text with EEA relevance)

(ONLY THE ENGLISH TEXT IS AUTHENTIC)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[1], and in particular Article 20(3) and (9) thereof,

Having regard to Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use[2], and in particular Article 34(1) thereof,

Having regard to Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use[3], and in particular Article 61(3) thereof,

Having regard to the changes to the terms of the decision granting the marketing authorisation requested by Eisai Limited in accordance with Article 61(3) of Directive 2001/83/EC,

Having regard to the opinion of the European Medicines Agency, formulated on 22 March 2018 by the Committee for Medicinal Products for Human Use,

Whereas:

(1) Medicinal products for human use authorised by the Member States must meet the requirements of Directive 2001/83/EC.

(2) A question has been referred to the European Medicines Agency under Article 31(1) of Directive 2001/83/EC, in a specific case where the interests of the Union are involved, as to whether the marketing authorisation concerned should be maintained, varied, suspended or withdrawn.

[1] OJ L 136, 30.4.2004, p. 1.
[2] OJ L 311, 28.11.2001, p. 67.
[3] OJ L 311, 28.11.2001, p. 67.

(3) As the procedure resulted from the evaluation of data relating to pharmacovigilance, the Pharmacovigilance Risk Assessment Committee of the European Medicines Agency issued a recommendation on 8 February 2018.

(4) The scientific assessment performed by the Committee for Medicinal Products for Human Use, the conclusions of which are set out in Annex IV to this Decision, shows that a decision should be taken amending the marketing authorisation for the medicinal product concerned.

(5) The European Medicines Agency's opinion is favourable to the variation of the terms of the decision granting the marketing authorisation as submitted by the marketing authorisation holder.

(6) Decision C(2001)818 should therefore be amended accordingly. The Community Register of Medicinal Products should also be updated.

(7) For the sake of clarity and transparency, it is appropriate, following the amendment of part or parts of the Annexes, to provide for a consolidated version thereof. The Annexes to Decision C(2001)818 should therefore be replaced.

(8) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Medicinal Products for Human Use,

HAS ADOPTED THIS DECISION:

Article 1

The marketing authorisation granted by Decision C(2001)818 of 29 March 2001 for the medicinal product “Targretin - bexarotene” is amended, on the basis of the scientific conclusions set out in the Annex IV to this Decision.

Article 2

Decision C(2001)818 is amended as follows:

1) Annex I is replaced by the text set out in Annex I to this Decision;

2) Annex II is replaced by the text set out in Annex II to this Decision;

3) Annex III is replaced by the text set out in Annex III to this Decision.

Article 3

This Decision is addressed to Eisai Limited, European Knowledge Centre, Mosquito Way, Hatfield, Hertfordshire AL10 9SN, United Kingdom.

Done at Brussels, 21.6.2018

For the Commission

Xavier PRATS MONNÉ
Director-General

CERTIFIED COPY
For the Secretary-General,

Jordi AYET PUIGARNAU
Director of the Registry
EUROPEAN COMMISSION